



6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

**[Docket ID No. EPA-HQ-OAR-2020-0312; FRL-10011-92-ORD]**

### **Call for Information on the Integrated Science Assessment for Lead**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice; call for information.

**SUMMARY:** The Environmental Protection Agency (EPA) is preparing an Integrated Science Assessment (ISA) as part of the review of the primary and secondary National Ambient Air Quality Standards (NAAQS) for Lead (Pb). The ISA will be completed by EPA's Office of Research and Development's Center for Public Health and Environmental Assessment (CPHEA). When final, the ISA is intended to update the previous Pb ISA (EPA/600/R-10/075F), published on June 26, 2013. Interested parties are invited to assist EPA in developing and refining the scientific information base for the review of the Pb NAAQS by submitting research studies and data that have been published, accepted for publication, or presented at a public scientific meeting since January 1, 2011.

**DATES:** All communications and information should be received by EPA by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Information may be submitted electronically, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions as provided in the section of this notice entitled **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** For information on the period of submission, contact the OAR Docket at the EPA Headquarters Docket Center; phone: 202-566-1742; fax:

202-566-9744; or email: a-and-r-Docket@epa.gov. For technical information, contact Evan Coffman; phone: 919-541-0567; fax: 919-541-1818; or email: Coffman.Evan@epa.gov; or Meredith Lassiter; phone: 919-541-3200; fax: 919-541-1818; or email: lassiter.meredith@epa.gov.

## **SUPPLEMENTARY INFORMATION:**

### *I. Information About the Document*

Section 108(a) of the Clean Air Act directs the Administrator to identify certain air pollutants which, among other things, “cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare”;<sup>1</sup> and to issue air quality criteria for them. The air quality criteria are to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air....”. Under section 109 of the Act, EPA is then to establish NAAQS for each pollutant for which EPA has issued criteria. Section 109(d)(1) of the Act subsequently requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health or welfare. EPA is also required to review and, if appropriate, revise the NAAQS, based on the revised air quality criteria (for more information on the NAAQS review process, see <https://www.epa.gov/naaqs>).

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<sup>1</sup> Under Clean Air Act section 302(h), welfare effects include, but are not limited to, “effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.”

EPA has established NAAQS for six criteria pollutants, including for lead (Pb). Periodically, EPA reviews the scientific basis for these standards by preparing an ISA (formerly called an Air Quality Criteria Document). The ISA provides the scientific basis for EPA's decisions, in conjunction with additional technical and policy assessments, on the adequacy of the current NAAQS and the appropriateness of possible alternative standards. Early steps in this process include announcing the beginning of this periodic NAAQS review and the development of the ISA, and EPA requesting that the public submit scientific literature that they want to bring to the attention of the Agency as it begins this process. The Clean Air Scientific Advisory Committee (CASAC), whose review and advisory functions are mandated by section 109(d)(2) of the Clean Air Act, is charged (among other things) with independent scientific review of the Agency's air quality criteria.

The ISA will build on the scientific assessment for the last review,<sup>2</sup> focusing on assessing the information newly available since that considered in the 2013 ISA. With regard to development of the ISA, the public is encouraged to assist in identifying relevant scientific information for the review by submitting research studies that were not part of the prior review, and have been published or accepted for publication in a peer-reviewed journal. The Agency is interested in obtaining information from new and emerging studies showing effects or no effects from Pb exposure. For example, the Agency is interested in information about studies of effects of controlled exposure to Pb, including in laboratory animals and *in vitro* systems; epidemiologic (observational) studies of associations of health outcomes with population exposures to Pb; and

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<sup>2</sup> The scientific assessment for the last review is documented in the Integrated Science Assessment for Lead (Final Report, July 2013), EPA/600/R-10/075F; 78 FR 38318, June 26, 2013.

studies of ecological effects of Pb exposure. With regard to health effect studies, of particular interest are those studies that address or provide new information on health outcomes for which the scientific evidence presented in the 2013 ISA supported a “causal relationship” or “likely to be causal relationship” with Pb, e.g., cognitive effects in children, cardiovascular effects, and immune system effects; endpoints with less overall evidence and/or notable uncertainties at the time of the 2013 Pb ISA, such as attention deficit hyperactivity disorder, neurodegenerative effects, and adult obesity; endpoints not previously identified in the 2013 Pb ISA; relationships between Pb exposure concentrations and occurrence of health-related endpoints; health effects associated with blood lead levels below 10 µg/dL and/or with near current exposure concentrations; Pb toxicokinetics and toxicokinetic modeling; information and data useful for assessing biological plausibility for Pb-related health effects; and identification of populations and life stages at increased risk of Pb-related health effects. For ecological effects of Pb, studies that address or provide new information on terrestrial and aquatic biota are of particular interest including, but not necessarily limited to, effects of Pb on vegetation, soil and aquatic fauna, communities and populations of microorganisms, plants, and animals, as well as research on fate and transport of Pb in environmental media, and exposure-response relationships between Pb in ambient air or other media and ecological endpoints.

Information particular to air-related pathways of human and ecological exposure, including those involving deposition, are also of interest to the Agency. Air-related pathways are those that include air and may also involve media other than air, including indoor and outdoor dust, soil, surface water and sediments, vegetation and biota. Air-related Pb pathways of human exposure include inhalation of ambient air or ingestion of food, water or other materials,

including dust and soil, containing Pb that has deposited from ambient air.

EPA also seeks recent information in other areas of Pb research such as human and ecological exposure assessment and exposure assessment methodologies, sources and emissions, chemistry and physics, sampling and analytical methodology, ambient concentrations and size distributions, including environmental media concentration changes in response to changes in Pb deposition, and other effects on public welfare or the environment not listed above.

The Agency also seeks information regarding the design and scope of the review of the air quality criteria and the primary (health-based) and secondary (welfare-based) Pb standards to ensure that it addresses key policy-relevant issues and considers the new science that is relevant to informing our understanding of these issues. The Agency also seeks new scientific information that may address key uncertainties identified in the last Pb NAAQS review, which are provided in the Policy Assessment (EPA-452/R-14, May 2014).<sup>3</sup> Other opportunities for submission of new peer-reviewed, published (or in-press) papers will be possible as part of public comment on the draft ISAs that will be reviewed by the CASAC.

## *II. How to Submit Technical Comments to the Docket at [www.regulations.gov](http://www.regulations.gov)*

Submit your materials identified by Docket ID No. EPA-HQ-OAR-2020-0312 by one of the following methods:

- [www.regulations.gov](http://www.regulations.gov): Follow the on-line instructions for submitting comments.
- E-mail: [a-and-r-Docket@epa.gov](mailto:a-and-r-Docket@epa.gov)
- Fax: 202-566-9744. Due to COVID-19, there may be a delay in processing

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<sup>3</sup> The 2014 Policy Assessment is available at:  
[https://www3.epa.gov/ttn/naaqs/standards/pb/data/140501\\_pa\\_pb\\_fin.pdf](https://www3.epa.gov/ttn/naaqs/standards/pb/data/140501_pa_pb_fin.pdf)

comments submitted by fax.

- Mail: Office of Air and Radiation (OAR) Docket (Mail Code: 28221T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460. The phone number is 202-566-1752. Due to COVID-19, there may be a delay in processing comments submitted by mail.

*Note:* The EPA Docket Center and Reading Room is currently in the reopening process. Visitors may be considered on an exception basis. Visitors must complete docket material requests in advance and then make an appointment to retrieve the material. Visitors will be allowed entrance to the Reading Room by appointment only, and no walk-ins will be allowed.

*Instructions:* Direct your comments to Docket ID No. EPA-HQ-OAR-2020-0312. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked “late,” and may only be considered if time permits. It is EPA's policy to include all materials it receives in the public docket without change and to make the materials available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless materials includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of

the materials that are placed in the public docket and made available on the Internet. If you submit electronic materials, EPA recommends that you include your name and other contact information in the body of your materials and with any disk or CD-ROM you submit. If EPA cannot read your materials due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider the materials you submit. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EPA's Docket Center homepage at [www.epa.gov/epahome/dockets.htm](http://www.epa.gov/epahome/dockets.htm).

*Docket:* Documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the OAR Docket in EPA's Headquarters Docket Center.

Dated: June 30, 2020.

**Wayne Cascio,**  
*Director,*  
*Center for Public Health and Environmental Assessment.*

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